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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,332	11/21/2000	Narmada Shenoy	038602-1060	9626

7590

07/18/2003

Beth A. Burrous  
FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, DC 20007-5109

EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/716,332

Applicant(s)

SHENOY ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the amendment of 19 JUNE 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,3-5,7,8,10,11,13-34,36,38-48 and 50-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48, 50-72, 76, 77, and 85-87 is/are allowed.
- 6) ☒ Claim(s) 73,74 and 78-84 is/are rejected.
- 7) ☒ Claim(s) 75 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48, and 50-87 are pending.
  2. Claims 73, 74, and 78-84 are rejected.
  3. Claims 75 are objected.
  4. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48, 50-72, 76, 77, and 85-87 are allowed.
- 

### ***Response to Arguments***

5. Applicants' arguments, including the response and amendments of June 19, 2003, with respect to claims 73, 74, and 78-84 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

6. Claim 75 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the term/phrase ionizable substituted indolinone. In addition, the instant specification does not describe what is meant by the term/phrase ionizable substituted indolinone other than those ionizable substituted indolinones as embraced by the instantly described compounds of Formula (I). Structural identifying characteristics of the term/phrase ionizable substituted indolinone are not disclosed except for those that are adequately described compounds of Formula (I). There is no evidence that there is any per se structure/function relationship between the term/phrase ionizable substituted indolinone other than those disclosed, namely ionizable substituted indolinones as embraced by the instantly described compounds of Formula (I). The instant specification does provide an adequate written description for the term/phrase of ionizable substituted indolinone. Accordingly, these claims fail to comply with the written description requirement.

9. Claims 78-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a "method of

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treating a protein kinase related disorder” by administering the ionizable substituted indolinones as embraced by the instantly described compounds of Formula (I). These claimed methods of treatment fail to meet the requirement for an adequate written description of the claimed invention as required by under 35 U.S.C. 112, first paragraph. There is insufficient descriptive support for the phrase a “method of treating a protein kinase related disorder”. In addition, the instant specification does not describe what is meant by the phrase a “method of treating a protein kinase related disorder” other than treating the cell of lung carcinoma, melanoma, glioma, ovarian, epidermal for humans and glioma of rats and epithelial murine carcinomas, as evidenced in Table 1.

Structural identifying characteristics of the phrase a “method of treating a protein kinase related disorder” are not disclosed except for those treating the cell of lung carcinoma, melanoma, glioma, ovarian, epidermal for humans and glioma of rats and epithelial murine carcinomas. There is no evidence that there is any per se structure/function relationship between the phrase a “method of treating a protein kinase related disorder” other than those disclosed, namely treating the cell of lung carcinoma, melanoma, glioma, ovarian, epidermal for humans and glioma of rats and epithelial murine carcinomas, as evidenced in Table 1. The instant specification does provide an adequate written description for the phrase of a “method of treating a protein kinase related disorder”. Accordingly, these claims fail to comply with the written description requirement. In the absence of some adequately described understanding of the types of protein kinase related disorders that are to be treated one skilled in the art would not have concluded that Applicants were in possession of the instantly claimed methods.

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***Allowable Subject Matter***

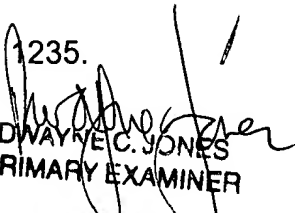
10. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48, 50-72, 76, 77, and 85-87 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
DWAYNE C. JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
July 18, 2003